

General Assembly

Amendment

January Session, 2013

LCO No. 7848

HB0652707848HD0

Offered by:

REP. SHARKEY, 88th Dist.

REP. ARESIMOWICZ, 30th Dist.

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To: Subst. House Bill No. 6527 File No. 229 Cal. No. 172

"AN ACT CONCERNING GENETICALLY ENGINEERED BABY FOOD."

- 1 Strike everything after the enacting clause and substitute the
- 2 following in lieu thereof:
- 3 "Section 1. Section 21a-92 of the general statutes is repealed and the
- 4 following is substituted in lieu thereof (Effective October 1, 2013):
- 5 For the purposes of this chapter, [and] section 21a-65, sections 2 and
- 6 3 of this act, and section 21a-102, as amended by this act, the following
- 7 terms shall have the meanings hereinafter specified:
- 8 (1) "Advertisement" means all representations disseminated in any
- 9 manner or by any means, other than by labeling, for the purpose of
- 10 inducing, or which are likely to induce, directly or indirectly, the
- 11 purchase of food, drugs, devices or cosmetics;

(2) (A) "Color additive" means a material which (i) is a dye, pigment or other substance made by a process of synthesis or similar artifice, or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral or other source, and (ii) when added or applied to a food, drug or cosmetic, or to the human body or any of its parts, is capable, alone or through reaction with other substance, of imparting color thereto, except that the term "color additive" does not include any material exempted by regulation under the federal act, or which the commissioner, by regulation, determines is used, or intended to be used, solely for a purpose or purposes other than coloring; (B) the term "color" includes black, white and intermediate grays, as well as all other colors; (C) nothing in subparagraph (A) of this subdivision shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical used, or intended to be used, solely because of its effect in aiding, retarding or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil which thereby affects its color, whether before or after harvest;

- 30 (3) "Commissioner" means the Commissioner of Consumer 31 Protection;
 - (4) "Contaminated with filth" applies to any food, drug, device or cosmetic not securely protected from dust or dirt, and as far as may be necessary, by all reasonable means, from all foreign or injurious contaminations;
 - (5) "Cosmetic" means (A) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any of its parts for cleansing, beautifying, promoting attractiveness or altering the appearance, and (B) articles intended for use as a component of any such articles; except that such term shall not include soap;
- 42 (6) "Device", except when used in subdivision (15) of this section 43 and in subsection (i) of section 21a-93, [subsection (f)] subdivision (6)

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of subsection (a) of section 21a-102, as amended by this act, subsection

- 45 (c) of section 21a-106 and subsection (c) of section 21a-112, means
- 46 instruments, apparatus and contrivances, including their components,
- 47 parts and accessories, intended (A) for use in the diagnosis, cure,
- 48 mitigation, treatment or prevention of disease in [man] humans or
- other animals, or (B) to affect the structure or any function of the body
- of [man] <u>humans</u> or other animals;
- 51 (7) "Director" means the director of the agricultural experiment 52 station;
- 53 (8) "Drug" means (A) articles recognized in the official United States
- 54 Pharmacopoeia, official Homeopathic Pharmacopoeia of the United
- 55 States or official National Formulary, or any supplement to any of
- 56 them; (B) articles intended for use in the diagnosis, cure, mitigation,
- 57 treatment or prevention of disease in [man] <u>humans</u> or other animals;
- 58 (C) articles, other than food, intended to affect the structure or any
- 59 function of the body of [man] <u>humans</u> or any other animal; and (D)
- articles intended for use as a component of any articles specified in this
- subdivision; but shall not include devices or their components, parts or
- 62 accessories;
- 63 (9) "Federal act" means the federal Food, Drug and Cosmetic Act, as
- 64 amended, Title 21 USC 301 et seq.: 52 Stat. 1040 et seq.;
- 65 (10) "Food" means (A) articles used for food or drink for [man]
- 66 <u>humans</u> or other animals, [and] (B) chewing gum, (C) infant formula,
- and [(C)] (D) articles used for components of any such article;
- 68 (11) "Food additive" means any substance the intended use of which
- 69 results or reasonably may be expected to result, directly or indirectly,
- 70 in its becoming a component or otherwise affecting the characteristics
- of any food, including any substance intended for use in producing,
- 72 manufacturing, packing, processing, preparing, treating, packaging,
- 73 transporting or holding food; and including any source of radiation
- 74 intended for any such use, if such substance is not generally

75 recognized, among experts qualified by scientific training and 76 experience to evaluate its safety, as having been adequately shown 77 through scientific procedures or, in the case of a substance used in 78 food prior to January 1, 1958, through either scientific procedures or 79 experience based on common use in food, to be safe under the 80 conditions of its intended use; except that such term does not include 81 (A) a pesticide chemical in or on a raw agricultural commodity; or (B) a 82 pesticide chemical to the extent that it is intended for use or is used in 83 the production, storage or transportation of any raw agricultural 84 commodity; or (C) a color additive; or (D) any substance used in 85 accordance with a sanction or approval granted prior to June 12, 1963, 86 or the federal Food, Drug and Cosmetic Act, the Poultry Products 87 Inspection Act (21 USC 451 et seq.) or the Meat Inspection Act of 88 March 4, 1907, as amended;

- (12) "Immediate container" shall not include package liners;
- 90 (13) "Infant formula" means a milk-based or soy-based powder, 91 concentrated liquid or ready-to-feed substitute for human breast milk 92 that is intended for infant consumption and is commercially available;
 - [(13)] (14) "Intrastate commerce" means any and all commerce within the state of Connecticut and subject to its jurisdiction, and shall include the operation of any business or service establishment;
 - [(14)] (15) "Label" means a display of written, printed or graphic matter upon the immediate container of any article, provided a requirement made by or under authority of this chapter that any information or other word or statement appear on the label shall not be considered to be complied with unless such information or other word or statement also appears on the outside container or wrapper, if any, of the retail package of such article, or is easily legible through the outside container or wrapper;
- [(15)] (16) "Labeling" means all labels and other written, printed or graphic matter (A) upon any article or any of its containers or

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wrappers, or (B) accompanying such article; provided, if an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then, in determining whether the labeling or advertisement is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device or sound, or any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual, and provided the representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment or dusting powder or for such other use as involves prolonged contact with the body;

[(16)] (17) "Natural food" means food (A) which has not been treated with preservatives, antibiotics, synthetic additives, artificial flavoring or artificial coloring; [and] (B) which has not been processed in a manner that makes such food significantly less nutritive; and (C) which has not been genetically-engineered, as defined in section 2 of this act. Processing of food by extracting, purifying, heating, fermenting, concentrating, dehydrating, cooling or freezing shall not, of itself, prevent the designation of such food as "natural food";

[(17)] (18) "New drug" means (A) any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in its labeling or (B) any drug the composition of which is such that such drug, as a result of investigation to determine its safety and effectiveness for use

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139 under such conditions, has become so recognized, but which has not, 140 otherwise than in such investigations, been used to a material extent or 141 for a material time under such conditions, except that the provisions of 142 this subsection pertaining to "effectiveness" shall not apply to any drug 143 which (i) was commercially sold or used in the United States on 144 October 9, 1962, (ii) was not a new drug as defined by this subsection 145 prior to the enactment of these provisions, and (iii) was not covered by 146 an effective application under section 21a-110 or under Section 355 of 147 the federal act, when such drug is intended solely for use under 148 conditions prescribed, recommended, or suggested in labeling with 149 respect to such drug on whichever of the above dates is applicable;

- [(18)] (19) "Official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them;
- [(19)] (20) "Organically grown" means produced through organic farming methods, which involve a system of ecological soil management and mechanical or biological methods to control insects, weeds, pathogens and other pests and which rely on crop rotation, crop residues, composted animal manures, legumes, green manures, composted organic waste or mineral-bearing rocks;
- [(20)] (21) "Person" includes any individual, partnership, corporation, limited liability company or association;
- [(21)] (22) "Pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances is an "economic poison" within the meaning of the federal Insecticide, Fungicide and Rodenticide Act, 7 USC 135-135k, and which is used in the production, storage or transportation of raw agricultural commodities;
- [(22)] (23) "Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored or otherwise treated in their unpeeled natural form prior to marketing;

[(23)] (24) The term "safe" has reference to the health of [man] human or animal;

- [(24)] (25) "Sale" means any and every sale and includes (A) manufacture, processing, packing, canning, bottling or any other production, preparation or putting up; (B) exposure, offer or any other proffer; (C) holding, storing or any other possessing; (D) dispensing, giving, delivering, serving or any other supplying; and (E) applying, administering or any other using.
- Sec. 2. (NEW) (*Effective October 1, 2013*) For purposes of this section, section 3 of this act, section 21a-102 of the general statutes, as amended by this act, and section 5 of this act:
 - (1) "Enzyme" means a protein that catalyzes chemical reactions of other substances without being destroyed or altered upon completion of such reactions;
 - (2) "Genetically-engineered" or "genetic engineering" means a process whereby any food intended for human consumption or any seed or seed stock that is intended to produce food for human consumption (A) is produced from an organism or organisms in which the genetics are materially altered through the application of: (i) In vitro nucleic acid techniques, including recombinant DNA (deoxyribonucleic acid) techniques, the direct injection of nucleic acid into cells or organelles, encapsulation, gene deletion and doubling, or (ii) fusion of cells that do not fall within the same taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection such as conjugation, transduction and hybridization; (B) is treated with a material described in subparagraph (A) of this subdivision for purposes that include, but are not limited to, increasing a raw agricultural commodity's resistance to herbicides and pesticides; or (C) contains an ingredient, component or substance described in subparagraph (A) of this subdivision;

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201 (3) "In vitro nucleic acid techniques" means techniques, including, 202 but not limited to, recombinant deoxyribonucleic acid techniques, that 203 use vector systems and techniques involving the direct introduction 204 into organisms of hereditary materials prepared outside the organisms 205 microinjection, such as macroinjection, chemoporation, 206 electroporation, microencapsulation and liposome fusion;

207 (4) "Organism" means any biological entity capable of replication, 208 reproduction or transferring genetic material;

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- (5) "Processed food" means any food intended for human consumption other than a raw agricultural commodity and includes any such food produced from a raw agricultural commodity that has been processed through canning, smoking, pressing, cooking, freezing, dehydration, fermentation or milling;
- (6) "Processing aid" means: (A) Any substance that is added to a food intended for human consumption during the processing of such food but that is removed in some manner from the food before the food is packaged in a finished form; (B) any substance that is added to such food during processing, that is converted into constituents normally present in the food, and that does not significantly increase the amount of the constituents naturally found in the food; or (C) any substance that is added to such food for its technical or functional effect in the processing but that is present in the finished food at insignificant levels and that does not have any technical or functional effect in the finished food;
- 225 (7) "Retailer" means a person or entity that engages in the sale of 226 food intended for human consumption to a consumer;
- (8) "Distributor" means a person or entity that sells, supplies, furnishes or transports food intended for human consumption in this state that such person or entity does not produce; and
- 230 (9) "Manufacturer" means a person who produces food intended for 231 human consumption or seed or seed stock that is intended to produce

food for human consumption and sells such item to a retailer or distributor.

Sec. 3. (NEW) (Effective October 1, 2013) (a) On and after the occurrence of the following: (1) Any five states, not including this state, enact a mandatory labeling law for genetically-engineered foods that is substantially consistent with the provisions of sections 1 to 4, inclusive, of this act, and (2) the aggregate population of such states is more than twenty-five million, and (3) two of such states border Connecticut or are New York and New Jersey, no person shall sell, offer for sale or distribute in this state any (A) food intended for human consumption, or (B) seed or seed stock that is intended to produce food for human consumption that is entirely or partially genetically-engineered, except a processed food subject to the provisions of this section solely because one or more processing aids or enzymes were produced or derived from genetic engineering, unless such food, seed or seed stock is labeled as follows: (i) In the case of such wholesale food that is not intended for retail sale, on the bill of sale accompanying such food during shipping, with the clear and conspicuous words: "Produced with Genetic Engineering"; (ii) in the case of such food for retail sale contained in a package, with the clear and conspicuous words: "Produced with Genetic Engineering"; (iii) in the case of such food that is a raw agricultural commodity, on the package offered for retail sale or, in the case of any such commodity that is not separately packaged or labeled, on the retail store shelf or bin that holds such commodity displayed for sale with the clear and conspicuous words: "Produced with Genetic Engineering"; and (iv) in the case of any such seed or seed stock, on the container holding the seed or seed stock displayed for sale or any label identifying ownership or possession of the commodity with the clear and conspicuous words: "Produced with Genetic Engineering". Such food labeling shall be displayed in the same size and font as the ingredients in the nutritional facts panel on the food label.

(b) The requirements of subsection (a) of this section shall not apply

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265 to any of the following:

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- 266 (1) Alcoholic beverages;
- (2) Food intended for human consumption that is not packaged for retail sale and that either: (A) Is a processed food prepared and intended for immediate consumption, or (B) is served, sold or otherwise provided in any restaurant or other food facility that is primarily engaged in the sale of food prepared and intended for immediate consumption;
- 273 (3) Farm products that are sold by a farmer or the farmer's agent to a 274 consumer at a pick-your-own farm, roadside stand, on-farm market or 275 farmers' market;
 - (4) Food consisting entirely of, or derived entirely from, an animal that was not genetically engineered, regardless of whether such animal was fed or injected with any genetically-engineered food or any drug that was produced through means of genetic engineering; and
- (5) Products derived from a single type of crop raised on a farm that produces not more than one million five hundred thousand dollars in gross sales for the farmer on whose farm such crop was raised in the previous twelve months.
 - (c) Any person selling, offering for sale or distributing in this state any food, seed or seed stock required to be labeled as provided in this section shall be responsible for ensuring that such food, seed or seed stock is so labeled.
- (d) The provisions of this section shall be enforced, within available appropriations, by the Commissioner of Consumer Protection.
- 290 (e) Any person found to knowingly violate this section shall be 291 liable for a civil penalty not to exceed one thousand dollars per day, 292 per product. Calculation of such civil penalty shall not be made or 293 multiplied by the number of individual packages of the same product

displayed or offered for retail sale. Civil penalties assessed under this section shall accrue and be assessed per each uniquely named, designated or marketed product.

- (f) Notwithstanding the provisions of subsection (c) of this section, a retailer shall not be liable for the failure to label pursuant to this section unless the retailer is the producer or the manufacturer of the genetically-engineered food, seed or seed stock and sells the genetically-engineered food under a brand it owns, unless the failure to label was knowing and wilful.
- 303 (g) The Commissioner of Consumer Protection may adopt 304 regulations, in accordance with the provisions of chapter 54 of the 305 general statutes, to implement and enforce the provisions of this 306 section.
- Sec. 4. Section 21a-102 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2013*):
 - (a) A food shall be deemed to be misbranded: [(a)] (1) If its labeling is false or misleading in any particular. A statement on the label or labeling either directly or indirectly implying that the product is recommended or endorsed by any agency of the federal or state government shall be considered misleading, unless the agency concerned has approved the statement prior to its use; [(b)] (2) if it is offered for sale under the name of another food; [(c)] (3) if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated; [(d)] (4) if its container is so made, formed or filled as to be misleading; [(e)] (5) if in package form, unless it bears a label containing [(1)] (A) the name and place of business of the manufacturer, packer or distributor; and [(2)] (B) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count; provided, under [subdivision (2) of this subsection] this subparagraph, reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations

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promulgated by the commissioner and director, acting jointly; [(f)] (6) if any information or other word or statement, required by or under authority of this chapter to appear on the label or labeling, is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs or devices, in the labeling, and in such terms, as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; [(g)] (7) if it purports to be or simulates or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 21a-100, unless [(1)] (A) it conforms to such definition and standard, and [(2)] (B) its label bears the name of the food specified in the definition and standard, and, so far as may be required by such regulations, the common names of optional ingredients, other than spices, flavoring and coloring, present in such food; [(h)] (8) if it purports to be or is represented as [(1)] (A) a food for which a standard of quality has been prescribed by regulations as provided by section 21a-100 and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; [or (2)] (B) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 21a-100, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; [(3)] or (C) a food for which no definition and standard of identity and no standard of quality has been prescribed by regulations as provided by section 21a-100, and it falls below the standard of purity, quality or strength which it purports or is represented to possess; [(i)] (9) if it is not subject to the provisions of [subsection (g)] subdivision (7) of this [section] subsection, unless its label bears [(1)] (A) the common or usual name of the food, if any, and [(2)] (B) if it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings and colorings, other than those sold as such, may be designated as spices, flavorings and colorings without naming each; provided, to the extent that compliance with the requirements of

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[subdivision (2) of this subsection] this subparagraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the commissioner and director, acting jointly; [(i)] (10) if it purports to be or is represented to be for special dietary uses, unless its label bears such information concerning its vitamin, mineral and other dietary properties as is necessary in order fully to inform purchasers as to its value for such uses, as provided by regulations promulgated by the commissioner and director, acting jointly; [(k)] (11) if it bears or contains any artificial flavoring, artificial coloring, artificial sweetening or chemical preservative, unless it bears labeling stating that fact; provided, to the extent that compliance with the requirements of this subsection is impracticable, exemptions shall be established by regulations promulgated by the commissioner and director, acting jointly; (12) if it is intended for human consumption and genetically-engineered, as defined in section 2 of this act, and does not bear labeling as required in accordance with section 3 of this act, unless (A) it is a food intended for human consumption produced without the producer's knowledge that a seed or other component of such food was geneticallyengineered, or (B) on or before July 1, 2019, it is a processed food, as defined in section 2 of this act, that is subject to the provisions of section 3 of this act, solely because it contains one or more materials that have been produced with genetic engineering, as defined in section 2 of this act, provided such genetically-engineered materials do not, in the aggregate, account for more than nine-tenths of one per cent of the total weight of the processed food.

(b) Seed or seed stock that is intended to produce food for human consumption shall be deemed misbranded if it is genetically-engineered, as defined in section 2 of this act, and does not bear labeling as required in accordance with section 3 of this act.

Sec. 5. Section 21a-99 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2013*):

393 All such proceedings for the enforcement, or to restrain violations,

of this chapter <u>and section 3 of this act</u> shall be by and in the name of the state of Connecticut."

This act shall take effect as follows and shall amend the following sections:		
Section 1	October 1, 2013	21a-92
Sec. 2	October 1, 2013	New section
Sec. 3	October 1, 2013	New section
Sec. 4	October 1, 2013	21a-102
Sec. 5	October 1, 2013	21a-99